

Role of Naloxone in Opioid Overdose Fatality Prevention

Purpose Statement - Prescription opioid use is becoming more prevalent in the U.S. Nearly 257 million prescriptions for prescription opioids were written in 2009 alone. While prescription opioid analgesics such as OxyContin and Vicodin are needed as a treatment for chronic pain, abuse rates have also risen, and overdose mortality rates closely correlate with opioid sales. In 2008, approximately 36,450 people died from drug overdoses. At least 14,800 of these deaths involved prescription opioid analgesics. Moreover, according to the Substance Abuse and Mental Health Services Administration, the number of Americans in 2009 aged 12 and older currently abusing pain relievers has increased by 20 percent since 2002.

Naloxone, a mu-opioid receptor antagonist, is an injectable medicine that can rapidly reverse the overdose of either prescription- (e.g., OxyContin) or illicit (e.g., heroin) opioids. It is currently the standard treatment for those who overdose on opioid drugs, but is most commonly used by trained medical personnel in emergency departments and on ambulances. The purpose of this meeting is to discuss whether naloxone should be made more widely available to trained laypersons in an effort to reduce deaths due to opioid overdose.

Meeting Goals

1. To initiate a public discussion about whether naloxone should be made more widely available outside of conventional medical settings to reduce opioid overdose fatalities. We will assemble academic, government, industry experts and patient advocates to:
 - Discuss at-risk populations for opioid overdose
 - Describe attempts by public health groups to curb the abuse of opioids, and
2. To identify issues related to wider naloxone availability including:
 - Regulatory issues
 - Potential health concerns
 - Social concerns
 - Legal concerns
 - Future research needs

Meeting Agenda
April 12, 2012

8:30 am Welcome and Opening Remarks

Peter Lurie, MD, MPH
Senior Advisor, Office of Policy and Planning
Office of Commissioner
Food and Drug Administration

8:50 am Panel 1 - "Naloxone Safety and Effectiveness in Treating Opioid Overdose"

- Which specific populations are at risk for opioid overdose?
- Which public health interventions have been successful in preventing or treating opioid overdose?

Moderator: Bob Rappaport, MD
Director
Division of Anesthesia, Analgesia and Addiction Products
Center for Drug Evaluation and Research
Food and Drug Administration

9:00 am Populations at Risk: Len Paulozzi, MD, MPH
Medical Epidemiologist
Division of Unintentional Injury Prevention
National Center for
Injury Prevention and Control
Centers for Disease Control and Prevention

9:20 am Public Health Interventions: Nicholas Reuter
Supervising Public Health Advisor
Division of Pharmacologic Therapy
Center for Substance Abuse Treatment
Substance Abuse and Mental Health
Services Administration

9:40 am Naloxone: Gregory Terman, MD, PhD
Effects and Side Effects Professor
Department of Anesthesiology
University of Washington

10:00 am Questions and Answers

10:10 am Break

10:30 pm Panel 2 – “Opioid Overdose Interaction with Naloxone in Extra-Medical Settings:
Review and Examples of Current Practices”

- What data describe the experience with the use of naloxone in treating opioid overdose?

Moderator: Wilson Compton, MD, MPE
Director, Division of Epidemiology, Services and
Prevention Research
National Institute on Drug Abuse
National Institutes of Health

10:40 am Overview, Criminal Justice
And Other Special Settings

Ingrid Binswanger, MD, MPH
Assistant Professor of Medicine
University of Colorado
Denver School of Medicine

11:00 am Bystander Overdose Education
And Naloxone Distribution
In Massachusetts

Alex Walley, MD
Assistant Professor of Medicine
Boston University
School of Medicine

11:20 am Project Renaissance: Overdose
Prevention among IDUs
In Kazakhstan

Nabila El-Bassel, MD
Professor of Social Work
Columbia University

11:40 am Questions and Answers

12:00 pm Lunch

1:00 pm Panel 3 - “Product Development Issues Related to Naloxone”

- What are the regulatory pathways to broader use of naloxone including new formulations?
- What issues need to be addressed when studying naloxone for the treatment of overdose?
- What has been the industry experience with product development?

Moderator: Douglas C. Throckmorton, MD
Deputy Director for Regulatory Programs
Center for Drug Evaluation and Research
Food and Drug Administration

Co-Moderator: Phil Skolnick, Ph.D., D.Sc (hon)
Director, Division of Pharmacotherapies
and Medical Consequences of Drug Abuse
National Institute on Drug Abuse

1:10 pm Naloxone for Outpatient use: Data Required to Support an NDA	Sharon Hertz, MD Deputy Director Division of Anesthesia, Analgesia and Addiction Products Food and Drug Administration
1:25 pm Expanded Access: OTC Status:	Andrea Leonard-Segal, MD Director, Division of Nonprescription Clinical Evaluation, Office of Nonprescription Products Food and Drug Administration
1:40 pm Development and Marketing: of Needleless Naloxone	Dan Wermeling, Pharm.D. Professor, University of Kentucky College of Pharmacy President and CEO, Alcomed, Inc.
1:55 pm Ethical and Regulatory Considerations For IN Naloxone	Robert (Skip) Nelson, MD Office of Pediatric Drugs, Office of the Commissioner
2:10 pm Questions and Answers	
2:30 pm	Break
2:45 pm	Open Public Hearing – Peter Lurie, Wilson Compton, Len Paulozzi
<ol style="list-style-type: none"> 1. Leo Beletsky, JD 2. Alice Bell, Prevention Point, Pittsburgh, PA 3. Dan Bigg, Chicago Recovering Alliance 4. Robert Childs, North Carolina, Harm Reduction Coalition 5. Phillip Coffin, University of Washington 6. Naburum Dasgupta, University of North Carolina, Chapel Hill 7. John Dombrowski, American Society of Anesthesiologists 8. Marianna Kate Duncan, Concerned Parent 9. Whitney Englander, Harm Reduction Coalition 10. Susan Gregory, Families Against Narcotics 11. Christopher Heneghan, Windham Harm Reduction Coalition 12. T. Stephen Jones, MD, Public Health Physician 13. Mark Kinzly, Roxbury Health Care Center 14. Terri Kroh, Center for Pharmacy Services, Pittsburgh 15. Steven Lankenau, Drexel University 16. Pamela Lynch, LLMSW 17. Thomas McNally, Windham Harm Reduction Coalition 18. Hillary McQuie, Harm Reduction Coalition 19. Marilee Murphy Odendahl 	

20. Joanne Peterson, Learn to Cope
21. Megan Ralston, Drug Policy Alliance
22. Jo L Sotheran, National Alliance for Medication Assisted Recovery
23. Roxanne Saucier, Surya Consulting
24. Sharon Stancliff, Harm Reduction Coalition
25. Eliza Wheeler, Harm Reduction Coalition
26. Azzi Momen, Open Society Foundation
27. Mary Torsch, Daniel Carl Torsch Foundation
28. Sherri French, GRASP, Maryland Chapter

3:45 pm Panel 4 – “Social and Legal Aspects of Wider Naloxone Availability”

- What are the lessons learned from other public health interventions?
- Should the use of naloxone be expanded?
- What are the societal, legal, and cost implications of broadened use of naloxone?
- What additional research is needed?

Moderator: Peter Lurie, MD, MPH
 Senior Advisor, Office of Policy and Planning
 Office of Commissioner
 Food and Drug Administration

3:50 pm Lessons Learned from Implementation of HPV Vaccine:
 Gregory Zimet, PhD
 Professor of Pediatrics
 Indiana University School of Medicine

4:05 pm Panel Discussion

- Edward W. Boyer, MD
 Professor of Emergency Medicine
 University of Massachusetts Medical School
- Fred Wells Brason, II, Chaplain
 President/CEO, Project Lazarus
 Project Director, NC Chronic Pain Initiative
 NC Community Care Network
- Scott Burris, JD
 Professor of Law
 Temple University Beasley School of Law
- Bertha Madras, PhD
 Professor of Psychobiology
 Harvard University Medical School)
- Captain Michael W. Bartoszek, MD
 Womack Army Center,
 Fort Bragg, NC

5:00 pm Questions and Answers

5:15 pm Closing Remarks

Sarah Wattenberg, MSW
Senior Advisor for Substance Abuse Policy
Office of the Assistant Secretary for Health